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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,120	07/18/2001	Dana Ault-Riche	25885-1751	1666

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,120	AULT-RICHE ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,49-54,93-95 and 99* is/are pending in the application.

4a) Of the above claim(s) *11-16,23,25-32,34,35,49-54,94,95 and 99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,17,19-22,24,33,36,37 and 93* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see Office Action*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant petition to rejoined Group III (Claims 49-54) with Group I (Claims 1-37, 93-95, and 99) was granted and the Office action mailed 2/25/2004 is vacated. Thus this Office Action is a Non-Final Office Action as indicated in the petition decision mailed 6/1/2004.

Status of Claims

2. Applicant's amendment filed 10/7/2003 is acknowledged and entered. Claims 2-4, 8-9, and 25 have been amended. It is noted that applicant designation of the claims 8-9 are improper since they are amended because claims 8-9 showed changes to the claims. Claims 8-9 should be designated as "currently amended" ***not*** "originally presented".

3. Claims 38-48, 55-92, and 96-98 were canceled and Claim 99 was added by the amendment filed on 12/27/2002.

4. Claims 1-37, 49-54, 93-95, and 99 are pending.

Election/Restrictions

5. Claims of the elected invention are 1-37, 49-54, 93-95, and 99.

6. Applicant has elected the following species for the elected invention (Claims 1-37, 49-54, 93-95, and 99) in the reply filed on 1-37, 49-54, 93-95, and 99:

a) Capture agents: antibodies

b) Oligonucleotide: '[o]ligonucleotide comprises a polypeptide-encoding region (*i.e.*, has formula 5'-E_m-3'), where each polypeptide that binds to a capture agent is encoded by a region designated E_m that is at least about 14 nucleotides'.

The traversal is on the ground(s) that "[F]irst, the oligonucleotides are not attached to the capture agent, and second, it makes no sense to elect a single capture agent or single oligonucleotide, since the claims are directed to combinations that include collections of each".

This is not found persuasive because the presently claimed combination can be interpreted at least two ways. The presently claimed array (i.e. combination) briefly recites a combination of capture agents and oligonucleotide wherein the oligonucleotide comprises nucleotides that encodes a preselected polypeptide to which the capture agent binds (Claims 1 and 17) (i.e. the oligonucleotides are "attached" to the capture agent). For example, the combination can be interpreted as an array of probes (capture agent) that binds (i.e. *the point of attachment to the capture agent*) to the analyte (oligonucleotide) or an array of probes that comprises of a combination of capture agent and oligonucleotide wherein they are 'link' (i.e. *the point of attachment to the capture agent*). Thus each interpretation combination comprises several structurally distinct species because within each genus of capture agents and oligonucleotides, there are structurally distinct species. The requirement is still deemed proper.

7. Claims 11-16, 23, 25-32, 34-35, 94-95, and 99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on 10/7/03.

Priority

8. This application claims benefit to a provisional application 60/219,183 filed 7/19/2000.

Information Disclosure Statement

9. The information disclosure statement(s) (IDS) submitted by applicant filed on 8/12/02; 10/9/02, 7/2/03, 6/18/2004, and 10/5/2004 are acknowledged and considered.

10. Claims 1-10, 17-22, 24, 33, 36-37, 49-54, and 93 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-10, 17-22, 24, 33, 36-37, and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 recites the limitation " a preselected polypeptides " in line 7. There is insufficient antecedent basis for this limitation in the claim 1.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 1-6, 8-9, 17, 20, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Huston et al. (Us Patent 5,084,398).

The instant claim 1 recites a combination. The combination comprises a plurality of capture agents and a plurality of oligonucleotides. Each capture agent specifically binds to a polypeptide. Each oligonucleotide comprises a sequence of nucleotides that encodes a preselected polypeptide wherein the preselected polypeptide binds the capture agent, and the oligonucleotides are single-stranded, double-stranded, or partially double-stranded.

The claimed combination is interpreted as "a composition of matters, which is defined as product, wherein the discrete physical structures or materials is the distinguishing characteristic. A composition may be a molecule(s), compound(s), solution(s), mixture(s), alloy(s), atom(s), etc. The limitation wherein the "capture agent specifically binds to a polypeptide" is interpreted as a functional limitation of the capture agent. The limitation wherein the "preselected polypeptide binds the capture agent" is interpreted as a functional limitation of the capture agent. Additionally, the phrase "a preselected polypeptide" and "a polypeptide" is interpreted as synonymous to each other.

Huston et al. disclose an array (refers to the presently claimed combination) comprises antibodies (refers to the presently claimed capture agents) and oligonucleotides that are encoded

with a protein-binding site specific to the antibodies (refers to claim 1) (see e.g. Abstract; col. 2, lines 10-23; col. 5, lines 24-37; fig. 2). The antibodies are immobilized on a solid support (refers to the instant claims 5-6) (see e.g. col. 2, lines 30-41; col. 5, lines 38-52). The amino acid sequence that is encode by the oligonucleotide has a length greater than 2, i.e. m of 5'-E_m-3' is greater than 2, (refers to the instant claims 24) and the oligonucleotide is single-stranded (see e.g. fig. 2). Therefore the array of Huston et al. anticipates the presently claimed combination.

15. Claims 1, 5, 7, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al. (US Patent 5,639,603).

The instant claims 1and 49 recite a combination. The combination comprises a plurality of capture agents and a plurality of oligonucleotides. Each capture agent specifically binds to a polypeptide. Each oligonucleotide comprises a sequence of nucleotides that encodes a preselected polypeptide wherein the preselected polypeptide binds the capture agent, and the oligonucleotides are single-stranded, double-stranded, or partially double-stranded. The instant claim 49 further comprise of a computer system with software for analyzing results of sorts.

The claimed combination is interpreted as "a composition of matters, which is defined as product, wherein the discrete physical structures or materials is the distinguishing characteristic. A composition may be a molecule(s), compound(s), solution(s), mixture(s), alloy(s), atom(s), etc. The limitation wherein the "capture agent specifically binds to a polypeptide" is interpreted as a functional limitation of the capture agent. The limitation wherein the "preselected polypeptide binds the capture agent" is interpreted as a functional limitation of the capture agent. Additionally, the phrase "a preselected polypeptide" and "a polypeptide" is interpreted as synonymous to each other.

Dower et al. disclose a collection of tagged compounds (refers to the presently claimed combination) and the method of making the tagged compounds (see e.g. Abstract; col. 1, lines 13-21; col. 3, line 66 to col. 4, line 18; col. 26, lines 12-42). The collection of tagged compounds comprises beads (refers to instant claims 5 and 7), single-stranded oligonucleotides (refers to the presently claimed oligonucleotides), and peptide sequences (refers to the presently claimed peptides) (see e.g. col. 3, line 66 to col. 4, line 18; col. 26, lines 12-42; col. 44, line 61 to col. 45,

line 39). The collection of tagged compounds was sorted by binding the peptides to an antibody using a fluorescence activated cell-sorting instrument (refers to the presently claimed computer system and claim 51) (see e.g. col. 26, lines 32-40; col. 31, lines 54-63; col. 45, lines 1-7). Thus the collection of tagged compounds of Dower et al. anticipates the presently claimed combination.

16. Claims 1-6, 8-10, 17-22, 33, 49-54, and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al. (US Patent 6,329,209 B1).

The instant claims 1 and 49-50 recite a combination. The combination comprises a plurality of capture agents and a plurality of oligonucleotides. Each capture agent specifically binds to a polypeptide. Each oligonucleotide comprises a sequence of nucleotides that encodes a preselected polypeptide wherein the preselected polypeptide binds the capture agent, and the oligonucleotides are single-stranded, double-stranded, or partially double-stranded. The instant claims 49 and 50 further comprise of a computer system with software for analyzing results of sorts.

The claimed combination is interpreted as "a composition of matters, which is defined as product, wherein the discrete physical structures or materials is the distinguishing characteristic. A composition may be a molecule(s), compound(s), solution(s), mixture(s), alloy(s), atom(s), etc. The limitation wherein the "capture agent specifically binds to a polypeptide" is interpreted as a functional limitation of the capture agent. The limitation wherein the "preselected polypeptide binds the capture agent" is interpreted as a functional limitation of the capture agent. Additionally, the phrase "a preselected polypeptide" and "a polypeptide" is interpreted as synonymous to each other.

Wagner et al. disclose an array of protein-capture agents wherein the protein-capture agent is immobilized on the substrate surface to form a plurality of patches of protein-capture agents on discrete, known regions (refers to the presently claimed addressable array) of the surface of a substrate (see e.g. Abstract; col. 3, lines 58-67 to col. 4, lines 1-2). The protein-capture agents are immobilized through an affinity tags that have specific affinity to the protein-capture agents onto the substrate surface (refers to claim 5) (see e.g. col. 20, lines 59-62; col. 21,

lines 19-). The affinity tags (refers to the presently claimed oligonucleotides) comprises of polypeptides that are encoded by a DNA sequence (see e.g. col. 21, lines 25-28; col. 60-64). Protein-capture agent includes antibodies (see e.g. col. 4, lines 48-67). The array can have any number of a plurality of different protein-capture agents (see e.g. col. 11, lines 1-11). For instance, an array comprise of about 10,000 patches would comprise of about 10,000 different protein-capture agents (see e.g. col. 11, lines 28-33). Therefore, the number of different protein-capture agents on an array will vary depending on the application desired (see e.g. col. 11, lines 12-13). Additionally, Wagner et al. disclose a detection unit and the array of protein-capture agents (see e.g. col. 33, line 49 to col. 34, line 9; col. 34, lines 44-59; fig. 8). The detection unit comprises a CPU (refers to the presently claimed computer system), and a CCD camera (refers to claims 52 and 54). Therefore the array of Wagner et al. anticipates the presently claimed combination.

17. Claims 1-8, 17-22, 24, 33, 36-37, 49-50, 53 and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Iris et al. (US Patent 6,403,309 B1).

The instant claims 1 and 49-50 recite a combination. The combination comprises a plurality of capture agents and a plurality of oligonucleotides. Each capture agent specifically binds to a polypeptide. Each oligonucleotide comprises a sequence of nucleotides that encodes a preselected polypeptide wherein the preselected polypeptide binds the capture agent, and the oligonucleotides are single-stranded, double-stranded, or partially double-stranded. The instant claims 49 and 50 further comprise of a computer system with software for analyzing results of sorts.

The claimed combination is interpreted as "a composition of matters, which is defined as product, wherein the discrete physical structures or materials is the distinguishing characteristic. A composition may be a molecule(s), compound(s), solution(s), mixture(s), alloy(s), atom(s), etc. The limitation wherein the "capture agent specifically binds to a polypeptide" is interpreted as a functional limitation of the capture agent. The limitation wherein the "preselected polypeptide binds the capture agent" is interpreted as a functional

limitation of the capture agent. Additionally, the phrase "a preselected polypeptide" and "a polypeptide" is interpreted as synonymous to each other.

Iris et al. discloses an array of antibody that captures oligonucleotide probes labeled with peptide tags (refers to oligonucleotide encoding polypeptide) (see e.g. Abstract; col. 1, lines 14-18; col. 2, lines 34-47). The solid phase surface comprises a plurality of loci (refers to the presently claimed addressable array), wherein each locus comprises an antibody specific to one or more of the peptides of the peptide label oligonucleotide probes (see e.g. col. 6, lines 28-31; col. 22, lines 23-29). The peptide tags are specific to the antibodies of the array (see e.g. col. 21, lines 29-39). Further, the oligonucleotide probes may be first hybridized to a target DNA before being capture by the addressable antibody arrays (see e.g. col. 15, lines 32-67 to col. 16, lines 1-11). Additionally, the array of Iris et al. comprises a computer that generates and stores the arrayed pattern of the array (refers to the presently claimed computer system and claim 53) (see e.g. col. 23, lines 18-25). Therefore, the array of Iris et al. anticipates the presently claimed combination.

Conclusion

18. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
December 15, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER